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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,674	05/23/2001	C. Frederick Battrell	5SMV41.1	1283

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EXAMINER	
SIEFKE, SAMUEL P	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

Office Action Summary	Application No.	Applicant(s)	
	09/863,674	BATTRELL ET AL.	
	Examiner	Art Unit	
	Samuel P Siefke	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 12/23/03 have been fully considered but they are not persuasive. Applicant argues, "Weigl does not disclose forming a combined solution which has a uniform composition across the width of the microfluidic channel." Specifically on col. 22, lines 48-54, Weigl discloses "Diffusion does act perpendicular to the flow direction, that is, perpendicular to the length so analyte particles in the sample stream and reference stream diffuse to the right and left, respectively, into indicator stream 70 and **may eventually become uniformly distributed across the width of flow channel 100** at uniform analyte particle diffusion area 120." This clearly states that there is a point (120) at which a uniform particle diffusion area occurs that is distributed across the width of the flow channel 100.

The Applicant argues, "Weigl does not disclose varying the flow rate of the first fluid, the second fluid or both the first and second fluids such that the concentration of the diffusible constituent in the combined solution varies along the length of the microfluidic channel." The Office would like to point to column 18, lines 43-59 wherein, Weigle states that varying the flow rates "for example, in cases of low test sensitivity wherein the sample contains a very low concentration of analyte and/or the detectable property is inherently same, a low fluorescence quantum yield, if the **indicator stream is flowing more slowly than the sample stream**, then the indicator substance in the indicator stream is effectively surrounded by a greater number of analyte particles for a longer period of time.... **In these cases it is preferable to have sample and reference**

streams pumped by same motor and the indicator stream pumped by different motor." This specifically indicates that the flow rates are varied in order to provide for the indicator to have a longer contact time with the sample.

It is the Offices position that Weigl discloses each and every limitation of claim 18-26.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims **18-26** are rejected under 35 U.S.C. 102(e) as being anticipated by Weigl et al. (USPN 6,171,865 B1).

Weigl discloses a simultaneous analyte determination apparatus that comprises: a first inlet (fig. 3, ref. 30), second inlet (fig. 3, ref. 20A) and third inlet (fig. 3, ref. 25A; downstream of 1st and 2nd inlet); and a first outlet (fig. 3, ref. 60); a first fluid comprising a diffusible constituent (fig. 3, ref. 80; col. 24, line 64-col. 25, line 46) flowing through

first inlet into a channel (fig. 3, ref. 100, flow is parallel); a second fluid flowing through a second inlet (fig. 3, ref. 20A, 70A) into the channel (100), providing a diffusion interface (fig. 3, ref. 140A) between first and second fluid wherein a diffusible constituent diffuse from the first fluid into the second fluid (col. 25, lines 24-28) such that the concentration (col. 3, lines 55-66) of diffusible species varies along the longitudinal axis of the diffusion interface (col. 25, lines 24-28); a third fluid inlet (fig. 3, ref. 25A), third fluid (75A) and the first fluid (80) surround the second fluid (70A) in the channel, wherein the diffusible constituents diffuse into the second fluid (fig. 3, ref. 140A and 145A; col. 25, lines 24-28); thus diluting the second fluid such that the concentration of the second fluid is gradually decreased with the distance from a section of the channel where first and second fluids contact each other (fig. 3, noting all references of the 1st, 2nd, and 3rd inlets moving toward the exit port; col. 24, line 64-col. 25, line 46). The first and third fluids are introduced through a first and third inlet from a common inlet (this common inlet will be described as the channel in which all the inlets come together in Fig. 3, ref. 100). The microfluidic device is located on a chip (col. 9, lines 62-67). Measurements can be taken on any part of the microfluidic device (col. 9, lines 1-22). The rate of flow of the first fluid and the second fluid remain content (col. 11, lines 32-51) or where the rate of flow is different (col. 16, lines 24-50; col. 18, lines 43-60). The diffusible constituent consists of a soluble compound, biological material (cells, proteins); (col. 10, line 48-col. 11, line 11). The fluid from the second inlet comprises undissolved particles (microbeads) (col. 14, lines 58-col. 15, line 12). Other important parts of the specification of the reference that describe the prior art or further the invention (col. 3,

lines 1-16 and 55-67; col. 5; col. 6, lines 4-14; fig. 1-7; col. 7-18; col. 22, line 13-col. 26, line 39; claims 1-22).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke

April 5, 2004

Jill Warden
Supervisory Patent Examiner
Technology Center 1700